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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,430	02/17/2000	Lawrence R. Green	15542-002310	6441

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Townsend And Townsend And Crew
TWO EMBARCADERO CENTER, 8TH FLOOR
San Francisco, CA 94111

EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	19

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/506,430	Applicant(s) GREEN ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-42* is/are pending in the application.

4a) Of the above claim(s) *23-27,36-38 and 40-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-22,28-35 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to the directives of paper No. 17 (filed 3/25/02), claims 18 and 20 have been amended.

Claims 18-22, 28-35, 39 are examined. Claims 23-27, 36-38, 40-42 remain withdrawn from consideration.

Applicants' arguments filed 3/25/02 have been considered and found persuasive in part. The rejection of claims 18, 19, 21, 22, 28-35, 39, over Nishimura or Ryan in view of Rodgers is withdrawn.

*

Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 f U.S. Patent No. 6,096,713. Although the conflicting claims are not identical, they are not patentably distinct from each other.

> The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application . See 37 CFR 1.78(d)

*

Claims 18-22, 28-35, 39 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 18 recites that R' and R" can be a "methyl alkyl ester" or an "ethyl alkyl ester". It is not clear what is meant by this. How is a "methyl alkyl ester" different from a methyl ester? If applicants perceive a difference, it would be helpful to provide an example of each. Alternatively, the claim should just recite methyl ester or ethyl ester. In addition, claim 18 permits R" to be any ester. Accordingly, the possibility of R" being a methyl or ethyl ester is best relegated to a dependent claim.

- Claim 18 lists various possibilites for R' and R". However, the claim as written is inaccurate and misleading. For example, it is stated that R' can be an amide. What is really intended is that R', taken together with the *alpha*-amino group of Glutamic acid, represents an amide. The claim could also be interpreted to mean that R' could be attached to the gamma-carboxyl group of glutamic acid, i.e., that the dipeptide Gln-Trp would be encompassed. Can the N-terminal amino acid be glutamine? The following is suggested:

  ...wherein

  R' represents an alkyl group or an aryl group,

  or R', taken together with the alpha-amino group of glutamic acid, represents an amide, or an imide;

  R" represents an alkyl group, an ether or an aryl group,

  or R", taken together with the carbonyl group of tryptophan represents an amide, an imide or an ester...

- Claim 18 is indefinite as to the process steps and endpoint. As it happens, the claim encompasses processes in which neither the time nor conditions are effective to inhibit neovascularization. Consider the following two hypothetical claims:

  100. A method of inhibiting neovascularization comprising administering a capsule containing compound "X" to a patient, wherein the composition of the capsule is such that compound "X" is never released, and consequently has no effect.

  101. A method of inhibiting neovascularization comprising

(a) placing a capsule containing compound "X" in the mouth of a patient,

(b) instructing the patient to leave the capsule in his mouth for 20 seconds, and to then remove the capsule from his mouth.

In the first of these, a composition containing "X" is administered, but "X" is never released, and so neovascularization will not result. In the second of these, the composition is in fact administered, but neither the time nor conditions of administration are effective to inhibit neovascularization. As it happens, claim 18 would encompass both of these possibilities.

This rejection can be remedied by reciting that the compound is administered *for a time and under conditions effective to inhibit neovascularization.* Any of the following could be used:

A method of inhibiting neovascularization comprising administering to a subject in need thereof a pharmaceutical composition comprising compound of the formula R'Glu-Trp-R" in combination with a pharmaceutically acceptable carrier for a time and under conditions effective to inhibit neovascularization.

A method of inhibiting neovascularization comprising administering to a subject in need thereof a pharmaceutical composition for a time and under conditions effective to inhibit neovascularization, wherein said composition comprises a compound of the formula R'Glu-Trp-R" in combination with a pharmaceutically acceptable carrier.

A method of inhibiting neovascularization comprising administering to a subject in need thereof a pharmaceutical composition comprising compound of the formula R'Glu-Trp-R" in combination with a pharmaceutically acceptable carrier, wherein said method the composition is administered to the subject for a time and under conditions effective to inhibit neovascularization.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 18, 19, 21, 22, 28-35, 39, are rejected under 35 U.S.C. §103 as being unpatentable over Haber [*Prog. Biochem. Pharmacol.* (1976), **12** (Drugs Affecting Renin-Angiotensin-Aldosterone Syst., Proc. Kanematsu Conf. Kidney, 5th), 16-32] in view of Rodgers (USP 5,716,935).

Haber discloses (e.g., page 17) that the peptide EWPRFQIPP inhibits the enzyme ACE. Haver does not disclose that inhibitors of ACE are also effective to inhibit neovascularization or angiogenesis. Rodgers discloses (col 3, line 5-10) that angiotensin stimulates neovascularization and angiogenesis. Rodgers does not disclose any of the peptides that are encompassed by the instant claims.

Accordingly, one of ordinary skill would have expected that an ACE inhibitor will inhibit neovascularization and angiogenesis.

Thus, the claims are rendered obvious.

- Reference "AW" was stricken from the IDS because of the absence of a translation. It is suggested that the IDS provide the citation for the abstract only.

- References "AT" and "AU" were stricken because they were not received.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600